


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3001239136	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:25-NOV-2015 DISTRICT: Seattle PRINTED BY FDA:03-DEC-2015								
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION							11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) SightLife 1200 6th Ave Ste 300 Seattle, Washington 98101 a. PHONE 206-838-4630 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps	Establishment Functions									
5. ENTER CORRECTIONS TO ITEM 4		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) SightLife Attn: Thomas D. Miller, B.S. 1200 6th Ave Ste 300 Seattle, Washington 98101 a. PHONE 206-838-4630 EXT _____		a. Bone										
7. ENTER CORRECTIONS TO ITEM 6		b. Cartilage										
b. PHONE _____		c. Cornea	X	X	X	X	X	X	X	X		
8. U.S. AGENT		d. Dura Mater										
a. E-MAIL _____		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Thomas D. Miller, B.S. b. E-MAIL tom.miller@sightlife.org c. TITLE VP of Quality and Regulatory Affairs d. DATE 24-NOV-2015		f. Fascia										
		g. Heart Valve										
		h. Ligament										
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		j. Pericardium										
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera	X	X	X	X	X	X	X	X		
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		n. Skin										
		o. Somatic Cell Therapy <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		p. Tendon										
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
		s. Amniotic Membrane					X		X	X		AmnioGraft, PROKERA
		t.										
		u.										
		v.										